

### **REMARKS/ARGUMENTS**

Reconsideration is respectfully requested of the Final Office Action of January 30, 2006, relating to the above-identified application.

It is noted with appreciation that Claims 19-27 have been allowed.

Claims 19 and 20 have been amended to correct the grammar in accordance with the Examiner's request.

It is noted that the rejection of Claims 1 to 27 under 35 U.S.C. § 103(a) in view of *Schreyer, et al.*, taken with *Logan, et al.*, *Signorini, et al.* and *Tsao* has been withdrawn.

The rejection of Claims 1 to 15 under 35 U.S.C. § 102(b) or 103(a) in view of *Tsao, et al.* (US 4,889,689) is traversed and reconsideration is respectfully requested.

Briefly summarized, *Tsao* discloses a stabilized aqueous hydrogen peroxide solution that is physiologically tolerable to the ocular environment. In col. 3, lines 51-68, it is defined what is to be understood by "physiologically tolerable to the ocular environment" and physiologically acceptable tonicity enhancing agents are taught for use as additives to obtain this intended result. The Official Action makes a point about the use of the word "may", in col. 3 at line 51, implying thereby that the tonicity enhancing agents are only optional ingredients. However, it is stated clearly that tonicity enhancing agents function to increase the comfort levels of the hydrogen peroxide solution in the eye of the patient, col. 3, lines 58 to 63. See in particular, Example 1 of *Tsao*, which contains several sodium compounds.

Further, while the claims of *Tsao* do not recite the presence of the tonicity enhancing agent that is not a basis to allege that the reference teaches the exclusion of tonicity agents. *Tsao*'s invention relates to the presence of the stabilizing agent diethylene triamine penta(methylene-

phosphonic acid). Hence, the claims of *Tsao* clearly focus on that feature. The presence of tonicity enhancing agents clearly falls into the category of conventional additives and would not ordinarily be included in the claims.

As is evident from Example 1 of the *Tsao* reference, about 0.87 wt-% sodium chloride is added resulting in a content of sodium ion of about 3400 wppm absolute, and taking into account the concentration of hydrogen peroxide in that solution of 3 wt-%, this correlates to about 110,000 wppm based on the weight of hydrogen peroxide in said solution. In Example 1, in addition to sodium chloride also sodium phosphate dibasic and sodium phosphate monobasic are added and, the pH is adjusted by adding sodium hydroxide or HCl. Consequently, *Tsao* clearly teaches an isotonic hydrogen peroxide solution of low concentration having a sodium ion content based on the weight of hydrogen peroxide that is higher by several orders of magnitudes (110,000 wppm) than the upper limit for the alkali metal concentration according to the claims herein. It follows that *Tsao* does not inherently teach a low alkali metal ion concentration; but on the contrary, *Tsao* teaches a very high alkali metal ion concentration in order to obtain an isotonic solution.

An invention has to be compared in its entirety, i.e. the combination of all features defined in the independent claims, with the prior art references as a whole, not just portions of the prior art. The claims of this application call for the combination of a low concentration of alkali and/or alkaline earth metals of less than 50 wppm, a specified defined amine content of less than 50 wppm and a concentration of anions or compounds that dissociate to form anions of at least 100 wppm. *Tsao* fails to describe this combination of features within the meaning of 35 U.S.C. § 102(b). Therefore, the *Tsao* reference is insufficient as a basis for a rejection of the present independent claims, as anticipated.

The Official Action takes the position that the claimed features are inherent in the prior art reference. The inherent teaching of a prior art reference is a question of fact and can arise in both the context of anticipation and obviousness. *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, (Fed. Cir. 1995). It is also well established that an allegation that a certain result or characteristic may occur or be present in the prior art is not a sufficient basis to establish the inherency of that particular result or characteristic. See, *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955 (Fed. Cir. 1993) which reversed a rejection because inherency was based on what would result due to optimization of conditions and not what was necessarily always present in the prior art. See also, *In re Oelrich*, 666 F.2d 578, 212 USPQ 323 (CCPA 1981). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. See, *In re Robertson*, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999).

In the present case, the extrinsic evidence is lacking.

In relying upon the theory of inherency, the burden is upon the examiners to provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. See, *Ex Parte Levy*, 17 USPQ2d 1461 (BPAI 1990) and MPEP Section 2112.

It is manifest from the cases quoted above that both the courts and the PTO have emphasized that in order to sustain a rejection based on inherency, the burden is upon the

examiner to establish that the claimed result would necessarily and inevitably result from the operation of the invention described in the referenced patent.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co., of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

In the Final Action, it is said, "The composition of *Tsao* '689 would inherently contain less than 50 wppm alkali metals or alkaline earth metals, since there is no indication in *Tsao* '689 that such metals are present."

This statement is in clear contradiction to Example 1 in the *Tsao* reference where clearly a high concentration of sodium ions is present. This also contradicts the disclosure in col. 3, lines 30 to 45, that is relied on in the Office Action for the proposition that the hydrogen peroxide solution disclosed in the *Tsao* reference contains more than 100 wppm anions. According to this disclosure in the reference, the stabilizing anions are present in form of the alkali metal or ammonium salts.

Consequently, if the anions are present at the high concentration of at least 100 wppm, then inevitably the corresponding counter ions, i.e. alkali metal ions or ammonium ions, have to be present in a similar amount.

A rejection based on inherent disclosure of a prior art reference is only proper if the combination of features can be directly and unambiguously derived as the inevitable result flowing from the teachings of the prior art references. Since alkali metal salts and ammoniums salts are disclosed as equivalent for the additional stabilizers (col. 3, lines 30-31) and since alkali metal

compounds are disclosed, also for adjusting the pH and the tonicity of the solution, it is not possible that the combination of features defined in applicants' claims is directly and unambiguously derivable from the teaching of *Tsao*. That is, the limitation of less than 50 wppm alkali metals and/or alkaline earth metals could not have been arrived at from the teachings of *Tsao*. On the contrary, an informed selection from amongst the many possibilities described in the *Tsao* reference and that is a selection not even remotely disclosed in *Tsao*, would have to be made in order to arrive at a concentration of anions of more than 100 wppm and an alkali metal concentration of less than 50 wppm. Such a combination would be the selection of ethylenediamine penta(methylenephosphonic acid) and not the salt of the acid in a concentration outside the preferred range of 0.006 to 0.02 weight percent in combination with a selection of a stabilizer in form of an ammonium salt in a concentration of more than 100 wppm. Further, and contrary to the teaching of the *Tsao* reference, a selection would have to be made that the solution is not isotonic to the eye environment.

Such an embodiment is neither disclosed nor directly and unambiguously derivable by a person skilled in the art from the overall disclosure in the *Tsao* reference. Consequently, a rejection based on inherency is fatally flawed.

Neither does *Tsao* render *prima facie* obvious the subject matter of Claim 1. In view of the fact that high amounts of alkali metal ions are shown to provide an isotonic hydrogen peroxide solution, as seen in Example 1, a person skilled in the art would not be taught by *Tsao* that a starting hydrogen peroxide solution should be used with a very low alkali metal ion content as required by the present invention. A person skilled in the art would immediately recognize that any commercially available hydrogen peroxide solution would not have enough sodium ions present in

order to fulfill the requirement of an isotonic solution, with the result that under any circumstances additional alkali metal, especially sodium salts like sodium chloride, would have to be added to the solution to obtain the result intended to *Tsao*.

Furthermore, the argument that *Tsao* does not mention alkali metal ions in the claims and, therefore, alkali metal ions need not be present is not a proper basis for a rejection based on 35 U.S.C. § 103(a). It is well known and also documented by the other cited prior art that commercial hydroperoxide solutions contain high amounts of alkali metal ions and/or amines; see 4,981,662 of record. Consequently, the fact that alkali metal ions are not discussed is no basis for alleging that they are, in fact, not present. Using commercial hydroperoxide solutions without any further treatment or selection of specific hydroperoxide solutions with a very low alkali metal ion content would inevitably result in an alkali metal ion concentration of above the limits as presently claimed. Furthermore, a person skilled in the art reading the *Tsao* reference would by no means be motivated to select a commercial hydroperoxide solution with explicitly low alkali metal ion concentration or to treat a commercial hydroperoxide solution in order to remove the alkali metal ions since according to the teaching of *Tsao* an isotonic hydroperoxide solution is most preferred. A person skilled in the art would immediately realize that, when making this solution, alkali metal ions have to be added in order to obtain the desired tonicity. Consequently, there is no reason at all to use expensive starting material or additional process steps in order to reduce the alkali metal ion concentration.

Therefore, there is no reason in the reference leading a person skilled in the art to start from a hydrogen peroxide solution that is extremely low in alkali metal ion content. Thus, the teaching of *Tsao* fails to render obvious the subject matter of present Claims 1 to 15. On the contrary, the

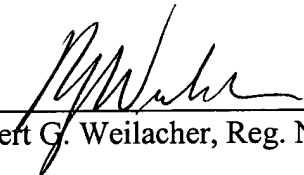
person skilled in the art is directed into a totally different direction, i.e. to use a hydrogen peroxide solution that has already an inherently high ionic concentration in order to reduce the amount of additional salts to be added when making the hydrogen peroxide solution.

The rejection of Claims 1 to 15 should therefore be reconsidered and withdrawn.

Favorable action at the Examiner's earliest convenience is respectfully requested.

Respectfully submitted,

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